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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/485,298	02/08/00	YAMAMOTO J	1422-411P

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EXAMINER	
CHAKRABARTI,A	
ART UNIT	**PAPER NUMBER**
1655	6

DATE MAILED: 05/31/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/485,298	Yamamoto et al.
Examiner	**Group Art Unit**
Arun Chakrabarti	1655

☒ Responsive to communication(s) filed on *Feb 8, 2000*

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *1-16* is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-16* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☒ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *4 & 5*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Priority

1. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No. 9-231885, filed on August 14, 1997 in Japan.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1 and 2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 2 are rejected as indefinite because the instantly claimed method lacks a final process step that clearly relates back to the preamble. For the method of claims 1 and 2 the preamble of the instantly claimed method is drawn to a method for amplifying a DNA while the final process step is that of presence of two or more kinds of nucleotide analogs or the presence of a compound for lowering Tm value of a double-stranded nucleic acid in the amplification

reaction mixture and it is thus unclear as to whether the instantly claimed method is drawn to amplifying a DNA or rather an added nucleotide analog or a compound for lowering Tm value of a double-stranded nucleic acid. Method claim requires a last step or phrase in the last step that states the accomplishments of the goals for the method which were stated in the method's preamble. Claims 1 and 2 lack such a last step and are confusing because the additional method step is not sufficiently set forth. While minute details are not required in method claims, at least the basic steps must be recited in a positive, active fashions. See Ex parte Erlich, 3 USPQ2d1011, p.1011 (Bd. Pat. Applicant. Int. 1986). It is suggested that an amended claim more clearly describing the intended steps be submitted.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-9 are rejected under 35 U.S.C 103 (a) over McDonough et al. (U.S. Patent 5,766,849) (June 16, 1998) in view of Pergolizzi et al. (U.S.Patent 5,658,764) (August 19, 1997).

McDonough et al teach a method for amplifying a DNA by polymerase chain reaction by the use of a DNA fragment comprising a nucleotide analog as a template, characterized in that the method for amplifying a DNA is carried out in the presence of a compound (DMSO) for lowering the *Tm* value of a double-stranded nucleic acid (Abstract and Examples , Column 12, lines 42-53 and Example 9, column 16, lines 14-42).

McDonough et al teach a method for amplifying a DNA characterized in that the DNA fragment is a cDNA prepared by reverse transcription reaction using an RNA as a template (Examples , Column 12, lines 42-53 and Example 9, column 16, lines 14-42).

McDonough et al do not teach the method for amplifying a DNA in the presence of two or more kinds of nucleotide analogs.

Pergolizzi et al teach the method for amplifying a DNA in the presence of two or more kinds of nucleotide analogs (7-Deaza-dGTP, inosine and 7-Deazainosine) (Column 8, lines 34-38) to be incorporated in a DNA strand in place of dGTP (Abstract and Example 1).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to substitute and combine the modified nucleotide analogues model of Pergolizzi et al with the methods of amplifying nucleic acids using modified nucleotide template

of McDonough et al ., since Pergolizzi et al state, "Use of this modified nucleotide significantly increased the amount of specific PCR product generated with this set of primers and permitted amplification and detection of the very large alleles present in affected individuals, the detection of which alleles is not possible by the prior methods (Column 9, lines 53-58)". An ordinary artisan would have been motivated by these express statements of Pergolizzi et al to combine the modified nucleotide analogues model of Pergolizzi et al with the methods of amplifying nucleic acids using modified nucleotide template of McDonough et al., in order to achieve the express advantages of modified nucleotide analogues, as noted by Pergolizzi et al , which provide significant increase in the amount of specific PCR product generated with a particular set of primers and permit amplification and detection of the very large alleles present in affected individuals, the detection of which alleles is not possible by the prior methods.

6. Claims 1-16 are rejected under 35 U.S.C 103 (a) over McDonough et al. (U.S. Patent 5,766,849) (June 16, 1998) in view of Pergolizzi et al. (U.S.Patent 5,658,764) (August 19, 1997) further in view Stratagene Catalog (1988, Page 39).

McDonough et al. in view of Pergolizzi et al. expressly teach the method claims of 1-9 including all the modified nucleotide templates, analogues and compounds for lowering the *Tm* value of a double-stranded nucleic acid as described above in detail.

McDonough et al. in view of Pergolizzi et al. et al. do not teach the motivation to combine all the reagents for amplifying a nucleic acid in the form of a kit.

Stratagene catalog teaches a motivation to combine reagents into kit format (page 39).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine a suitable container and all the modified nucleotide templates, analogues and compounds for lowering the *Tm* value of a double-stranded nucleic acid , into a kit format as discussed by Stratagene catalog since the Stratagene catalog teaches a motivation for combining reagents of use in an assay into a kit, "Each kit provides two services: 1) a variety of different reagents have been assembled and pre-mixed specifically for a defined set of experiments. Thus one need not purchase gram quantities of 10 different reagents, each of which is needed in only microgram amounts, when beginning a series of experiments. When one considers all of the unused chemicals that typically accumulate in weighing rooms, desiccators, and freezers, one quickly realizes that it is actually far more expensive for a small number of users to prepare most buffer solutions from the basic reagents. Stratagene provides only the quantities you will actually need, premixed and tested. In actuality, the kit format saves money and resources for everyone by dramatically reducing waste. 2) The other service provided in a kit is quality control". (page 39, column 1).

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti, Ph.D., whose telephone number is (703) 306-5818. The examiner can normally be reached on 7:00 AM-4:30 PM from Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-7401.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Arun Chakrabarti,

Patent Examiner,

May 19, 2000

JEFFREY FREDMAN
PRIMARY EXAMINER